

§ 799.1

40 CFR Ch. I (7–1–98 Edition)

- 799.2475 2-Mercaptobenzothiazole.
- 799.2700 Methyl ethyl ketoxime.
- 799.3300 Unsubstituted phenylenediamines.
- 799.4360 Tributyl phosphate.
- 799.4440 Triethylene glycol monomethyl ether.

Subpart C—Testing Consent Orders

- 799.5000 Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.
- 799.5025 Testing consent orders for mixtures without Chemical Abstracts Service Registry Numbers.

Subpart D—Multichemical Test Rules

- 799.5055 Hazardous waste constituents subject to testing.
- 799.5075 Drinking water contaminants subject to testing.

Subparts E–G [Reserved]

Subpart H—Health Effects Test Guidelines

- 799.9135 TSCA acute inhalation toxicity with histopathology.
- 799.9346 TSCA subchronic inhalation toxicity.
- 799.9370 TSCA prenatal developmental toxicity.
- 799.9380 TSCA reproduction and fertility effects.
- 799.9420 TSCA carcinogenicity.
- 799.9510 TSCA bacterial reverse mutation test.
- 799.9530 TSCA in vitro mammalian cell gene mutation test.
- 799.9538 TSCA mammalian bone marrow chromosomal aberration test.
- 799.9539 TSCA mammalian erythrocyte micronucleus test.
- 799.9620 TSCA neurotoxicity screening battery.
- 799.9780 TSCA immunotoxicity.

AUTHORITY: 15 U.S.C. 2603, 2611, 2625.

SOURCE: 49 FR 39817, Oct. 10, 1984, unless otherwise noted.

Subpart A—General Provisions

§ 799.1 Scope and purpose.

(a) This part identifies the chemical substances, mixtures, and categories of substances and mixtures for which data are to be developed, specifies the persons required to test (manufacturers, including importers, and/or processors), specifies the test substance(s) in each case, prescribes the tests that are required including the test standards,

and provides deadlines for the submission of reports and data to EPA.

(b) This part requires manufacturers and/or processors of chemical substances or mixtures (“chemicals”) identified in subpart B to submit letters of intent to test, exemption applications, and study plans in accordance with EPA test rule development and exemption procedures contained in part 790 of this chapter and any modifications to such procedures contained in this part.

(c) This part requires manufacturers and/or processors of chemicals identified in subpart B to conduct tests and submit data in accordance with the test standards contained in this part in order to develop data on the health and environmental effects and other characteristics of these chemicals. These data will be used to assess the risk of injury to human health or the environment presented by these chemicals.

(d) This part contains certain TSCA test guidelines which are cross-referenced in the test rules contained in this part.

[49 FR 39817, Oct. 10, 1984, as amended at 62 FR 43824, Aug. 15, 1997]

§ 799.2 Applicability.

This part is applicable to each person who manufactures or intends to manufacture (including import) and/or to each person who processes or intends to process a chemical substance or mixture identified in subpart B for testing during the period commencing with the effective date of the specific chemical test rule until the end of the reimbursement period. Each set of testing requirements in subpart B specifies whether those requirements apply to manufacturers only, to processors only, or to both manufacturers and processors.

§ 799.3 Definitions.

The definitions in section 3 of the Toxic Substances Control Act (TSCA) and the definitions of § 790.3 of this chapter apply to this part.

§ 799.5 Submission of information.

Information (letters, study plans, reports) submitted to EPA under this part must bear the Code of Federal

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Regulations section number of the subject chemical test rule (e.g., § 799.1285 for Cumene) and must be addressed to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 401 M St., SW., Washington, DC 20460.

[60 FR 34467, July 3, 1995]

§ 799.10 Test standards.

Testing required under subpart B must be performed using a study plan prepared according to the requirements of parts 790 and 792 of this chapter unless modified in specific chemical test rules in subpart B. All raw data, documentation, records, protocols, specimens and reports generated as a result of a study under subpart B must be developed, reported, and retained in accordance with TSCA Good Laboratory Practice Standards (GLP's) in part 792 of this chapter. These items must be made available during an inspection or submitted to EPA upon request by EPA or its authorized representative. Laboratories conducting testing for submission to the Agency in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA GLP's. Sponsors must notify the laboratory that the study is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the test abide by the TSCA GLP standards. In accordance with § 792.12 of this chapter, a certification concerning adherence to the TSCA GLP's must be submitted to EPA.

§ 799.11 Availability of test guidelines.

(a) The TSCA and FIFRA guidelines for the various study plans are available from the National Technical Information Service (NTIS). Address and telephone number: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650).

(b) The OECD guidelines for the various study plans are available from the

following address: OECD Publication and Information Center, 1750 Pennsylvania Ave., NW., Washington, DC 20006 (202-724-1857).

§ 799.12 Test results.

Except as set forth in specific chemical test rules in subpart B of this part, a positive or negative test result in any of the tests required under subpart B is defined in the TSCA test guidelines published by NTIS.

§ 799.17 Effects of non-compliance.

Any person who fails or refuses to comply with any aspect of this part or part 790 is in violation of section 15 of TSCA. EPA will treat violations of Good Laboratory Practice Standards as indicated in § 792.17 of this chapter.

§ 799.18 Chemicals subject of test rules or consent orders for which the testing reimbursement period has passed.

The following table lists substances and mixtures that have been the subjects of section 4 testing actions and for which the testing reimbursement period has terminated (sunset). The FEDERAL REGISTER citation in the table is for the final rule/consent order that includes the particular substance for which the sunset date listed in the table below applies. Section 12(b) export notification is no longer required for these substances and mixtures. Substances that are the subjects of two or more section 4 testing actions may have section 4 reimbursement or section 12(b) export notification requirements that have not sunset; see subparts B, C, and D of this part to determine if certain other section 4 testing requirements apply. Additionally, section 12(b) export notification may also be triggered by proposed or final action under TSCA section 5, 6, or 7 (in addition to final actions under section 4); see 40 CFR part 707, subpart D for further information regarding the TSCA section 12(b) export notification requirements.

CAS No.	Chemical Name	FR cite	Sunset dates
	C-9 Aromatic Hydrocarbon Fraction ¹	50 FR 20662, 5/17/85	Aug 13, 1994
62-53-3	Aniline	53 FR 31804, 8/19/88	July 27, 1994
71-55-6	1,1,1-Trichloroethane	49 FR 39810, 10/10/84	June 29, 1992